Contains Nonbinding Recommendations

Draft Guidance on Calcium Carbonate; Famotidine; Magnesium Hydroxide

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the Office of Generic Drugs.

Active Ingredient: Calcium carbonate; Famotidine; Magnesium hydroxide

Dosage Form; Route: Tablet; chewable; oral

Recommended Studies: Two studies

1. Type of study: Fasting

Design: Single-dose, two-way crossover in vivo

Strength: 800 mg/10 mg/165 mg

Subjects: Normal healthy males and females, general population

Additional comments: Tablets should be chewed completely before swallowing

2. Type of study: Fed

Design: Single-dose, two-way crossover in vivo

Strength: 800 mg/10 mg/165 mg

Subjects: Normal healthy males and females, general population

Additional comments: Same as above

Analytes to measure (in appropriate biological fluid): Famotidine in plasma

Bioequivalence based on (90% CI): Famotidine

Waiver request of in vivo testing: Berry-flavored and tropical fruit-flavored chewable tablets based on (i) acceptable bioequivalence studies on the mint-flavored chewable tablets, (ii) the formulations are proportionally similar in their active and inactive ingredients, except for the flavoring and coloring agents, and (iii) acceptable in vitro dissolution testing of all flavors for all three components (calcium carbonate, famotidine, and magnesium hydroxide)

Dissolution test method and sampling times: The dissolution information for this drug product can be found on the FDA-Recommended Dissolution Methods Web site, available to the public at the following location: http://www.accessdata.fda.gov/scripts/cder/dissolution/. Conduct comparative dissolution testing on 12 dosage units each of all flavors of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application (ANDA).